DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 1, 2015

MIACOM DIAGNOSTICS GMBH
EVE BLÖMEKE
CLINICAL TRIALS & REGULATORY AFFAIRS MANAGER
MEROWINGERPLATZ 1A
DÜSSELDORF 40225
GERMANY

Re: K150031
Trade/Device Name: Hemofish Masterpanel
Regulation Number: 21 CFR 866.2660
Regulation Name: Microorganism differentiation and identification device
Regulatory Class: I
Product Code: JSS, MCS, MDK
Dated: August 28, 2015
Received: August 31, 2015

Dear Ms. Blömeke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ribhi Shawar -S

For Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150031

Device Name
hemoFISH Masterpanel

Indications for Use *(Describe)*
hemoFISH Masterpanel is a qualitative nucleic acid hybridization assay performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as determined by Gram stain and is intended for the identification of the following species / genera / families:

Gram-positive	Gram-negative
Staphylococcus spp.	Enterobacteriaceae
Staphylococcus aureus	Escherichia coli
Streptococcus spp.	Klebsiella pneumoniae

The hemoFISH Masterpanel is indicated as an aid in the diagnosis of specific agents of bacteremia and results should be used in conjunction with other clinical and laboratory findings. Positive hemoFISH Masterpanel results do not rule out co-infection with organisms not included in the hemoFISH Masterpanel. The hemoFISH Masterpanel is not intended to monitor treatment for bacteremia.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not identified by the hemoFISH Masterpanel, and for species determination of Staphylococcus spp., Streptococcus spp., and Enterobacteriaceae that are not identified by the hemoFISH Masterpanel.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

(As Required by 21 CFR 807.92)

1. Submitter:

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40225 Düsseldorf
Germany
Phone: +49 211 3015 5795
Fax: +49 211 2989 143

2. Contact Person:

Eve Blömeke

3. Summary Preparation Date:

September 30, 2015

4. Device Name and Classification:

Generic Name: Blood Culture Identification Kit

Trade Name: hemoFISH Masterpanel

Classification: Class I

Product Code: JSS – Kit, Identification, Enterobacteriaceae
MCS – DNA-Probe, Staphylococcus aureus
MDK – DNA-Probe, Reagents, Streptococcal

Regulation Numbers: 866.2660, 866.3700, 866.3740

5. Substantial Equivalence Information:

Predicate device name(s) and predicate 510(k) number:

Predicate Device Name	510(k) number
Gram-Negative QuickFISH, AdvanDx, Inc.	K123418

Comparison with Predicate:

Item	miacom Device	Predicate QuickFISH
Intended Use	Blood culture identification	Same
Species	Staphylococcus spp. S. aureus Streptococcus spp. Enterobacteriaceae E. coli K. pneumoniae	E. coli K. pneumoniae P. aeruginosa
Technology	Fluorescence in situ hybridization (rRNA)	Same
Probe type	Self-reporting DNA probes labeled with green or red fluorophore.	Self-reporting PNA probes labeled with green or red fluorophore.
Sample	Positive Blood culture	Same
Interpretation	Visual by fluorescence microscopy	Same
Controls	Rotating Controls S. aureus ATCC 9144 P. aeruginosa ATCC 10145 E. coli ATCC 14948 S. agalactiae ATCC 12403 K. pneumoniae, ATCC 13883	Positive Control E. coli K. pneumoniae P. aeruginosa

6. Device Description:

The hemoFISH Masterpanel identifies bacteria within 30 minutes directly from positive blood cultures.

The methodology is based on classical fluorescence in-situ hybridization (FISH) combined with the usage of fluorescently labeled molecular beacons.

A solution of fluorescently labeled molecular DNA beacons is dispensed on fixed and perforated cells prepared from a blood culture. The hybridization is carried out at 52°C for 10 minutes. Submerging the slide into a bath containing a stop solution ceases the reaction. Adding a drop of Mounting Medium to each field prevents fading of fluorescence. After applying a cover slip, the slide is ready for examination using fluorescence microscopy.

7. Intended use(s):

hemoFISH Masterpanel is a qualitative nucleic acid hybridization assay performed directly on blood culture samples identified as positive by a continuous monitoring blood culture system that demonstrates the presence of organisms as determined by Gram stain and is intended for the identification of the following species / genera / families:

Gram-positive	Gram-negative
Staphylococcus spp.	Enterobacteriaceae
Staphylococcus aureus	*Escherichia coli*
Streptococcus spp.	*Klebsiella pneumoniae*

The hemoFISH Masterpanel is indicated as an aid in the diagnosis of specific agents of bacteremia and results should be used in conjunction with other clinical and laboratory findings. Positive hemoFISH Masterpanel results do not rule out co-infection with organisms not included in the hemoFISH Masterpanel. The hemoFISH Masterpanel is not intended to monitor treatment for bacteremia.

Subculturing of positive blood cultures is necessary to recover organisms for susceptibility testing and epidemiological typing, to identify organisms in the blood culture that are not identified by the hemoFISH Masterpanel, and for species determination of *Staphylococcus* spp., *Streptococcus* spp., and Enterobacteriaceae that are not identified by the hemoFISH Masterpanel.

8. Indication(s) for use:

hemoFISH Masterpanel is indicated as an aid in the diagnosis of bacteremia.

9. Performance Characteristics:

Non-clinical studies

Analytical Inclusivity

The inclusivity of hemoFISH was determined using 120 representative reference strains.

In summary, hemoFISH correctly identified:

- Staphylococci other than *S. aureus* strains comprising *Staphylococcus arlettae, Staphylococcus capitis, Staphylococcus chromogenes, Staphylococcus condiment, Staphylococcus epidermidis, Staphylococcus equorum* subsp. *equorum*, *Staphylococcus gallinarum, Staphylococcus haemolyticus, Staphylococcus hominis* subsp. *hominis, Staphylococcus intermedius, Staphylococcus kloosii,*

Staphylococcus lentus, Staphylococcus lugdunensis, Staphylococcus lutrae, Staphylococcus microti, Staphylococcus pasteuri, Staphylococcus piscifermentans, Staphylococcus pseudointermedius, Staphylococcus pulvereri = vitulinus, *Staphylococcus rostri, Staphylococcus saprophyticus, Staphylococcus sciuri, Staphylococcus simiae, Staphylococcus succinus* subsp. *succinus* and *Staphylococcus xylosus*;

whereas the following 2 subspecies were identified as *S. aureus*:

Staphylococcus schleiferi subsp. *coagulans*
Staphylococcus schleiferi subsp. *schleiferi*

- *S. aureus* strains

- *Streptococcus* strains comprising *Streptococcus agalactiae, Streptococcus anginosus, Streptococcus australis, Streptococcus bovis, Streptococcus constellatus, Streptococcus dysgalactiae, Streptococcus equi, Streptococcus equinus, Streptococcus gallolyticus, Streptococcus gordonii, Streptococcus infantarius, Streptococcus infantis, Streptococcus mitis, Streptococcus mutans, Streptococcus oralis, Streptococcus parasanguinis, Streptococcus pasteurianus, Streptococcus pneumoniae, Streptococcus porcinus, Streptococcus pseudopneumoniae, Streptococcus pyogenes, Streptococcus sanguinis, Streptococcus suis, Streptococcus urinalis* and *Streptococcus vestibularis*

- Enterobacteriaceae other than *E. coli* and *K. pneumoniae* (comprising *Buttiauxella gaviniae, Cedeceae davisiae, Citrobacter freundii, Citrobacter koseri, Cronobacter muytjensi, Cronobacter sakazakii, Edwardsiella tarda, Enterobacter aerogenes, Enterobacter asburiae, Enterobacter cancerogenus, Enterobacter cloacae* subsp. *cloacae*, *Enterobacter cloacae* subsp. *dissolvens*, *Enterobacter gergoviae, Enterobacter hormaechei, Enterobacter/Pluralibacter pyrinus, Escherichia (Shimwella) blattae, Escherichia hermanii, Escherichia vulneris, Ewingella americana, Hafnia alvei, Klebsiella oxytoca, Kluyvera ascorbata, Leclercia adecarboxylata, Morganella morganii, Pantoea (Enterobacter) agglomerans, Plesiomonas shigelloides, Proteus hauseri, Proteus mirabilis, Proteus penneri, Proteus vulgaris, Providencia (Proteus) acalifaciens, Providencia (Proteus) rettgeri, Rahnella aquatilis, Raoultella planticola, Raoultella terrigena, Salmonella abony, Salmonella bongori, Salmonella choleraesuis, Salmonella enterica-heidelberg, Salmonella enterica-paratyphi, Salmonella typhimurium, Salmonella vellore, Serratia fonticola, Serratia liquefaciens, Serratia marcescens, Serratia plymuthica, Serratia proteamaculans* and *Yokenella regensburgei*

whereas the following species were identified as Other:
Tatumella ptyseos
whereas following species were identified as *E. coli*:
Escherichia albertii
Escherichia fergusonii
Shigella boydii
Shigella flexneri
whereas following species were identified as *K. pneumoniae*:
Klebsiella variicola

- *Escherichia coli* strains

- *Klebsiella pneumoniae* strains, incl. subsp. *ozaenae* and *rhinoscleromatis*

Analytical Specificity

The analytical specificity (exclusivity) of each of the 6 Beacons was determined using 215 strains representing clinical relevant species and/or species selected based on sequence similarities from *in silico* analysis. False positives results were observed with the following organisms:

Staphylococcus Beacon reacting with *Macrococcus caseolyticus*.

S. aureus Beacon reacting with *Staphylococcus schleiferi* subsp. *schleiferi*, *Staphylococcus schleiferi* subsp. coagulans and *Macrococcus caseolyticus*.

E. coli Beacon reacting with *Shigella boydii*, *Shigella flexneri*, *Escherichia albertii* and *Escherichia fergusonii*.

K. pneumoniae Beacon reacting with *K. variicola*.

Streptococcus Beacon reacting with *Leuconostoc carnosum*, *Leuconostoc mesenteroides* and *Lactococcus* (*Streptococcus*) *lactis*.

Limit of Detection

The limit of detection (LoD) was assessed for each target species by testing blood culture bottles spiked with reference strains of *S. epidermidis, S. aureus, S. pneumoniae, S. agalactiae, E. coli, K. pneumoniae, P. mirabilis*. For each species, ≥19/20 replicates (≥95%) were positive at 10^5 CFU/mL.

Reproducibility - Precision & Accuracy

Microscope slides with smears of blood cultures spiked with *S. aureus, S. pneumoniae, S. agalactiae, E. faecalis, E. coli, K. pneumoniae, P. aeruginosa, S.*

maltophilia and *A. baumanii*, respectively, were prepared. The slides (3 slides/strain) were tested by 2 different operators on 2 x five consecutive days in accordance with the hemoFISH procedure for a total of 90 tests per strain.

The Reproducibility Study results are summarized in Table 1 below:

Table 1. Reproducibility

Organisms/Probe	Failure Rate	Reproducibility
Staphylococcus	0% (0/90)	100% (90/90) 95.9-100%
S. aureus	0% (0/90)	100% (90/90) 95.9-100%
Streptococcus	0.6% (1/180)	99.4% (179/180) 96.9-99.9%
Enterobacteriaceae	0.6% (1/180)	99.4% (178/179) 96.6-99.9%
E. coli	1.3% (1/90)	100% (89/89) 95.9-100%
K. pneumoniae	0% (0/90)	98.9% (89/90) 94.0-99.8%
Other	0.3% (1/360)	100% (359/359) 98.9-100%

In summary, 99.8% (808/810) tests yielded valid test results of which 99.8% (806/808) were correct. The two invalid results with *S. maltophilia* and *E. coli*, respectively, were due to positive reaction with the Negative Control. The two incorrect results were: *S. agalactiae* identified as 'Other' and *K. pneumoniae* identified as Other Enterobacteriaceae.

Co-infection

Positive blood cultures were prepared with two target organisms that are identified in the same microscope field (*S. aureus* and *E. coli* or *S. pneumoniae* and *K. pneumoniae*). One organism was inoculated at a level close to the LoD and the other at 10^3-10^9 CFU/ml or vice versa. The blood culture vials were incubated until they turned positive and then tested according the hemoFISH procedure.

All assay results were as expected, indicating that the hemoFISH Masterpanel is capable of correctly identifying mixed cultures of *E. coli* and *S. aureus* or *S. pneumoniae* and *K. pneumoniae* that are detected in the same field when the target levels are above the LoD of the assay.

Clinical studies

Method comparison of hemoFISH Masterpanel to routine methods

The performance of hemoFISH Masterpanel versus routine laboratory methods was assessed in 3 clinical laboratory studies using a total of 609 monomicrobial and 55 polymicrobial prospective blood culture bottles as well as 61 in-house spiked (monomicrobial) blood culture bottles. The total number of monomicrobial blood cultures that were analyzed was 670. The results from testing the prospective blood cultures are shown in Table 2 and for the prospective and spiked samples combined in Table 3. The polymicrobial cultures were analyzed separately as shown in Table 4. The studies included BACTEC Plus Aerobic/F and Anaerobic/F, and VersaTREK REDOX 1 and 2 blood culture bottles.

Table 2. Agreement with routine identification for 609 monomicrobial blood cultures (in-house spiked blood cultures excluded)

		Routine Identification						
		S. aureus (69)	CNS[1] (167)	Strep.[2] (67)	E. coli (94)	K. pneu (36)	Other entero[3] (41)	Other[4] (135)
HemoFISH	S. aureus	69	2					
	Other Staph		160					1
	Streptococci			67	1			1
	E. coli				90			1
	K. pneu					36		
	Other entero				1		41	1
	Other		5		3			131[5]
Sensitivity		100%	95.8%	100%	95.7%	100%	100%	97.0%
		69/69	160/167	67/67	90/94	36/36	41/41	131/135
95% CI		94.7-100%	91.6-98.0%	94.6-100%	89.6-98.3%	90.4-100%	91.4-100%	92.6-98.8%
Specificity		99.6%	99.8%	99.6%	99.8%	100%	99.6%	98.3%
		538/540	441/442	540/542	514/515	573/573	566/568	466/474
95% CI		98.7-99.9%	98.7-100%	98.7-99.9%	98.9-100%	99.3-100%	98.7-99.9%	96.7-99.1%

[1]CNS comprises the following members of the coagulase negative staphylococci that were identified to the species level by standard laboratory methods: *S. auricularis, S. capitis, S. caprae, S. carnosus, S. epidermidis, S. haemolyticus, S. hominis, S. hominis* subsp. *novobiosepticus, S. lugdunensis, S. pettenkoferi, S. saccharolyticus, S. simulans, S. warneri*

[2]Strep. comprises the following members of Streptococci that were identified to the species level by standard laboratory methods: *S. agalactiae, S. alactolyticus, S. anginosus, S. bovis II, S. dysgalactiae* subsp. *equisimilis, S. gallolyticus* subsp. *pasteurianus, S. gordonii, Streptococcus group G, S. intermedius, S. lutetiensis, S. mitis, S. oralis, S. parasanguinis, S. pneumoniae, S. pyogenes, S. salivarius, S. sanguinis, S. thermophilus, S. vestibularis*

[3]Other entero comprises the following members of Enterobacteriaceae that were identified to the species level by standard laboratory methods: *Enterobacter cloacae, Klebsiella oxytoca, Proteus mirabilis, Proteus vulgaris, Salmonella enterica* subsp. I *Enteridis, Salmonella enterica* subsp. I *(enterica) oranienburg, Salmonella enterica* subsp. I *(enterica) typhimurium, Salmonella* Group B*, Serratia marcescens*

[4]Other comprises the following organisms that were identified to the species/genus level by standard laboratory methods: *Abiotrophia defectiva, Acinetobacter* spp. including *A. baumannii, Actinomyces meyeri, Actinomyces meyeri* subsp*. naeslundi, Aerococcus, Bacillus* spp. including *B. cereus, B. circulans, B. coagulans, B. megaterium, B. lincheniformis, B. subtilis* var. *pumilis, B. thuringiensis, Bacteroides caccae, Bacteroides distasonis (fragilis* group*), Bacteroides fragilis, Bacteroides ovatus, Bacteroides thetaiotaomicron, Bacteroides vulgatus, Candida albicans, Clostridium* spp. including *Clostridium bifermentas, Corynebacterium* spp. including *C. amycolatum, C. matruchoti, C. xerosis, Enterococcus faecalis, Enterococcus faecium, Enterococcus gallinarum, Enterococcus raffinosus, Elizabethkingia meningoseptica, Fusobacterium* spp*. including Fusobacterium nucleatum, Granulicatella adiacens, Kocuria kristinae, Kocuria varians, Kroppenstedtia eburnea, Leuconostoc pseudomesenteroides, Micrococcus luteus, Moraxella catarrhalis, Pasteurella multocida, Pediococcus pentosaceus, Peptostreptococcus asaccharolyticus, Prevotella disiens, Propionibacterium* spp.

including *Propionibacterium acnes, Pseudomonas aeruginosa, Rothia detocariosa, Stenotrophomonas acidaminiphila, Stenotrophomonas maltophilia.*

[5] Includes 1 sample that was positive by the reference method for *C. albicans*. Based on *in silico* analysis, the expected hemoFISH result with blood cultures that are positive for *C. albicans* when no bacterial species is present is "Fail" due to the absence of hybridization of the Eubacterial probe (refer to Interpretation of results).

Table 3. Comparison of hemoFISH results with routine identification for 670 monomicrobial blood cultures (prospective and spiked samples combined)

		Routine Identification						
		S. aureus (74)	CNS[1] (174)	Strep.[2] (76)	E. coli (96)	K. pneu (38)	Other entero[3] (64)	Other[4] (148)
HemoFISH	S. aureus	74	2					
	Other Staph		167					1
	Streptococci			76	1			1
	E. coli				92			1
	K. pneu					38		
	Other entero				1		62	1
	Other		5		3		2	144[5]
Positive agreement		100% 74/74	96.0% 167/174	100% 76/76	95.8% 92/96	100% 38/38	96.9% 62/64	97.3% 144/148
95% CI		95.1-100%	91.9-98.0%	95.2-100%	89.8-98.4%	90.8-100%	89.3-99.1%	93.3-98.9%
Negative agreement		99.7% 594/596	99.8% 495/496	99.7% 592/594	99.8% 573/574	100% 632/632	99.7% 604/606	98.1% 512/522
95% CI		98.8-99.9%	98.9-100%	98.8-99.9%	99.0-100%	99.4-100%	98.8-99.9%	96.5-99.0%

[1]CNS comprises the following members of the coagulase negative staphylococci that were identified to the species level by standard laboratory methods: *S. auricularis, S. capitis, S. caprae, S. carnosus, S. epidermidis, S. gallinarum, S. haemolyticus, S. hominis, S. hominis* subsp. *novobiosepticus, S. lugdunensis, S. pettenkoferi, S. saccharolyticus, S. simulans, S. warneri, S. xylosus*

[2]Strep. comprises the following members of Streptococci that were identified to the species level by standard laboratory methods: *S. agalactiae, S. alactolyticus, S. anginosus, S. bovis II, S. dysgalactiae* subsp. *equisimilis, S. gallolyticus* subsp. *pasteurianus, S. gordonii, Streptococcus* group G, *S. intermedius, S. lutetiensis, S. mitis, S. mutans, S. oralis, S. parasanguinis, S. pneumoniae, S. pyogenes, S. salivarius, S. sanguinis, S. thermophilus, S. vestibularis*

[3]Other entero comprises the following members of Enterobacteriaceae that were identified to the species by level standard laboratory methods: *Citrobacter amalonaticus, Citrobacter braakii, Citrobacter farmer, Citrobacter freundii, Citrobacter gillenii, Citrobacter koseri, Citrobacter murliniae, Citrobacter rodentium, Citrobacter youngae, Cronobacter muytjensi, Enterobacter cloacae, Klebsiella oxytoca, Morganella morganii, Proteus mirabilis, Proteus vulgaris, Providencia stuartii, Salmonella abony, Salmonella enterica* subsp. I *Enteridis, Salmonella enterica* subsp. I *(enterica) oranienburg, Salmonella enterica* subsp. I *(enterica) typhimurium, Salmonella* Group B*, Salmonella vellore, Serratia marcescens, Yersinia enterocolitica*

[4]Other comprises the following organisms that were identified to the species/genus level by standard laboratory methods: *Abiotrophia defectiva, Acinetobacter* spp. including *A. baumanii A. haemolyticus, A. iwoffii, A. junii, Actinomyces meyeri, Actinomyces meyeri* subsp*. naeslundi, Aerococcus, Bacillus* spp. including *B. cereus, B. circulans, B. coagulans, B. megaterium, B. lincheniformis, B. subtilis* var. *pumilis, B. thuringiensis, Bacteroides caccae, Bacteroides distasonis* (*fragilis* group), *Bacteroides fragilis, Bacteroides ovatus, Bacteroides thetaiotaomicron, Bacteroides vulgatus, , Candida albicans, Clostridium* spp. including *Clostridium bifermentas, Corynebacterium* spp. including *C. amycolatum, C. matruchoti, C. xerosis, Enterococcus faecalis, Enterococcus faecium, Enterococcus gallinarum, Enterococcus raffinosus, Elizabethkingia meningoseptica, Fusobacterium* spp. including *Fusobacterium nucleatum, Granulicatella adiacens, Kocuria kristinae, Kocuria varians, Kroppenstedtia eburnea, Leuconostoc pseudomesenteroides, Micrococcus luteus, Moraxella catarrhalis, Pasteurella multocida, Pediococcus pentosaceus, Peptostreptococcus asaccharolyticus, Prevotella disiens, Propionibacterium* spp. including *Propionibacterium acnes, Pseudomonas aeruginosa, Rothia detocariosa, Stenotrophomonas acidaminiphila, Stenotrophomonas maltophilia.*

[5] Includes 1 sample that was positive by the reference method for *C. albicans*. Based on *in silico* analysis, the expected hemoFISH result with blood cultures that are positive for *C. albicans* when no bacterial species is present is "Fail" due to the absence of hybridization of the Eubacterial probe (refer to Interpretation of results).

Table 4. Comparison of hemoFISH results with routine identification for 55 polymicrobial blood cultures

		Routine Identification						
		S. aureus	CNS	Strep.	E. coli	K. pneu	Other entero	Other
HemoFISH	S. aureus	2						
	Other Staph		14					
	Streptococci			7				
	E. coli				13			2*
	K. pneu					11		
	Other entero						4	
	Other							8
	Negative	1	7*	1	2	1	10	20

* 1 blood culture contained a mixture of *S. epidermidis* and *E. faecalis* and scored false negative for *S. epidermidis* and misidentified *E. faecalis* as *E. coli*.

10. Conclusion:

The hemoFISH Masterpanel has similar intended use and indications and as the predicate QuickFISH kit.

The performance of the hemoFISH Masterpanel is substantially equivalent to that of routine laboratory methods.